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COVIDIEN

510(K) SUMMARY

1. 510(k) Owner:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Telephone: (508) 261 – 6596
Fax: (508) 261 – 6596

Contact: Wing Ng
Title: Manager, Regulatory Affairs
Date Prepared: March 01, 2012

2. Device:

Trade Names: Mahurkar™ Elite Acute Dual Lumen Catheter
Mahurkar™ Elite Acute Triple Lumen Catheter
Common Name: Central Venous Catheter
Classification Name: Non-Implanted Hemodialysis Catheter (MPB)
Non-Implanted Triple Lumen Hemodialysis Catheter (NIE)
Regulation Number: 21 CFR 876.5540
Product Code(s): MPB, NIE
Classification: Class II

3. Predicate Devices:

Proposed Device	Predicate Device
Mahurkar™ Elite Acute Dual Lumen Catheter	Mahurkar™ Q Plus 13.5 Fr Dual Lumen Acute Dialysis Catheter (K030209)
Mahurkar™ Elite Acute Triple Lumen Catheter	Mahurkar™ High Pressure Triple Lumen Acute Dialysis Catheter (K102605)

4. Device Description:

The Mahurkar™ Elite Acute Dual Lumen Catheter features a two lumen design. The proximal end has color-coded adapters to indicate arterial and venous flow. The adapters are connected to extension tubes which are available in curved or straight configurations. The extension tubes are connected to the hub which is joined to a dual lumen shaft available in pre-curved and straight configurations. The shaft extends to side slots near the distal tip. The dual lumen catheter is available in 12.0 Fr or 13.5 Fr outer diameters and a variety of implant lengths ranging from 13 cm to 30 cm. It is offered as a single device or as convenience kits.

The Mahurkar™ Elite Acute Triple Lumen Catheter features a three lumen design. The proximal end has color-coded adapters to indicate arterial flow, venous flow, and medial infusion. The adapters are connected to extension tubes which are available in curved or straight configurations. The extension tubes are connected to the hub which is joined to a triple lumen shaft that extends to side slots near the distal tip. The triple lumen catheter is available in 12.5 Fr outer diameter and a variety of implant lengths ranging from 13 cm to 30 cm. It is offered as a single device or as convenience kits.

5. Intended Use:

The Mahurkar™ Elite Acute Dual Lumen Catheter is intended to be used for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar™ Elite Acute Triple Lumen Catheter is intended to be used for short-term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring, and pressure injection of contrast media. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media.

6. Technological Characteristics:

The proposed devices have the same technological characteristics as compared to their respective predicate devices.

7. Performance Data:

Bench top functional and performance testing was completed to support substantial equivalence between the proposed device and the current device. The test regimen evaluated the devices for cleaning agent compatibility, lock solution compatibility, dynamic flow, column strength, clamp functionality, shaft stiffness, tensile strength at various locations, and resistance to kink, leak, burst, catheter collapse, and fatigue. Additionally, the triple lumen catheter has been evaluated for central venous pressure monitoring performance and simulated injection of contrast media. The results of the performance testing show that the proposed devices continue to meet the relevant product specifications.

Biocompatibility testing per ISO 10993: Biological Evaluation of Medical Devices was completed to support biocompatibility of the proposed device. The results of the biocompatibility testing show that the proposed devices continue to be biocompatible for its intended use.

The results of functional, performance, and biocompatibility testing support the determination of substantial equivalence.

8. Conclusion:

Based on non-clinical testing results, Covidien has demonstrated that the proposed Mahurkar™ Elite Acute Catheters are substantially equivalent to its respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Wing Ng
Manager, Regulatory Affairs
Covidien
15 Hampshire Street
MANSFIELD MA 02048

APR - 4 2012

Re: K120674
Trade/Device Name: Mahurkar™ Elite Acute Dual Lumen Catheter
Mahurkar™ Elite Acute Triple Lumen Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB, NIE
Dated: March 1, 2012
Received: March 5, 2012

Dear Mr.Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine and ChloraPrep, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K120674

Section 4
Indications for Use Statement

510(k) Number (if known): K120674

Device Name: Mahurkar™ Elite Acute Dual Lumen Catheter
Mahurkar™ Elite Acute Triple Lumen Catheter

Indications for Use:

The Mahurkar™ Elite Acute Dual Lumen Catheter is indicated for short-term central venous access for hemodialysis, apheresis, and infusion.

The Mahurkar™ Elite Acute Triple Lumen Catheter is indicated for short-term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring, and pressure injection of contrast media. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120674